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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,675	06/21/2006	Bandi Parthasaradhi Reddy	H1089/20035	9298

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PHILADELPHIA, PA 19103-2212

EXAMINER
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SACEY, EBENEZER O

ART UNIT	PAPER NUMBER
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1624

NOTIFICATION DATE	DELIVERY MODE
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07/09/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/596,675	<b>Applicant(s)</b> PARTHASARADHI REDDY ET AL.	
	<b>Examiner</b> EBENEZER SACKY	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-24 and 37-58 is/are allowed.
- 6) ☒ Claim(s) 1-21, 25-36 and 59-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of the Claims**

Claims 1-67 are pending.

This is in response to applicant's amendment filed on 04/05/10.

### ***Claim Rejections - 35 USC § 112***

The rejection of claims 1-21 under 35 U.S.C. 112 second paragraph has been withdrawn in view of the amendment and remarks filed on 04/05/10.

### **Claim Rejections - 35 U.S.C. § 103**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-21 and 59-62 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al., U.S. Patent Number 4,831,031 in view of Howard et al., "Synthesis of <sup>3</sup>H- and <sup>14</sup>C-Labelled CP-88,059:" A POTENT ATYPICAL ANTIPSYCHOTIC AGENT; Journal of Labelled Compounds and Radiopharmaceuticals; Vol. XXXIV, No. 2; pages 117-125 for the reasons set forth in the previous office action mailed on 10/07/09.

4.

#### **Claim Rejections - 35 U.S.C. § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 25-36 and 63-67 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Busch et al., (WO 03/070246) and Lowe et al., U.S. Patent Number 4,831,031 each taken alone for the reasons set forth in the previous office action mailed on 10/07/09.

### ***Response to Amendment/Remarks***

Applicant's arguments filed 04/05/10 have been fully considered but they are not deemed persuasive. Applicants argue that the combination of the Lowe '031' patent and the Howard reference do not teach or suggest all the limitations of the claims. Contrary to applicant's assertion, '031' teaches the preparation of ziprasidone as claimed herein. The only difference being the absence of the use of a silylated agent as required of compound of formula (III) (reactant). However, this deficiency in '031' was remedied by Howard et al., wherein the reference teaches the use of triethylsilane compound during the preparation of ziprasidone. Applicants should note that the limitations of claims 1-21 such as the neutralizing agent, sodium carbonate and tertiary amines has been provided by '031' as noted column 2, lines 43-48. Moreover, it is well settled that consideration of a reference is not limited to the preferred embodiments, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art to one skilled in the art. Applicants have not provided any side by side comparison showing superior results from the current invention.

Applicants next argue that there is no motivation for the skilled artisan to alter the methods of '031' or Howard et al., to arrive at the claimed method. In response to applicant's argument, it must be recognized that to the skilled artisan, any judgment on obviousness is in a sense necessarily a reconstruction. However, so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper (motivation). See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Additionally, there is nothing of record or statement in the references which states that the preparation of ziprasidone is only "limited" to specific reactants as applicants allege. Moreover, applicants have not argued that the reactants of '031' and Howard cannot not yield ziprasidone as claimed herein and therefore the compounds cannot be made.

With reference to the rejection based on '246' and '031' applicants again argue that the combined references do not teach or suggest all the limitations of the claims and further, there is no motivation to combine the two references. Again, the skilled artisan would have reasonably arrived at the current invention with the knowledge of the combined teachings of '031' and '246' noting that '031' teaches the necessarily solvents such as the tertiary amines and carbonates recited in column 2, lines 40-49. As previously reiterated, the solvents of claims 8-10, 13 and 14 and bases of claims 16 and 17 are known and are obvious modifications well within the purview of the skilled artisan. Applicants should note that slight differences in the references' may serve to

differentiate the current invention from that of the references but, does not serve to remove the relied upon references from under 35 U.S.C. 103.

***Allowable Subject Matter***

None of the prior art teaches or suggest silylated reactants of claims 22-24 and the process claims of 37-58.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to EBENEZER SACKKEY whose telephone number is (571)272-0704. The examiner can normally be reached on 7.30-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone

Art Unit: 1624

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Ebenezer O. Sackey/  
Patent Examiner, AU 1624.**

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**